



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0922; FRL-9910-50]

Sodium bisulfate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of sodium bisulfate when used as an inert ingredient in antimicrobial formulations on food contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils at no more than 2,000 ppm in final formulation. Exponent on behalf of Ecolab, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium bisulfate.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0922, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency

14P-0096

Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0922 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0922, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of January 16, 2013 (78 FR 3377) (FRL-9375-4), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (*PP* IN-10526) by Ecolab, Inc., 370 N. Wabasha Street, St. Paul, MN 55102. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of sodium bisulfate (CAS Reg. No. 7681-38-1) when used as an inert ingredient in antimicrobial pesticide formulations applied to food contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils at no more than 2,000 ppm in final formulation. That document referenced a summary of the petition prepared by Exponent, 1150 Connecticut Ave., NW., Suite 1100, Washington, DC 20036, the petitioner, which is available in the docket, <http://www.regulations.gov>.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human

health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sodium bisulfate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sodium bisulfate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by sodium bisulfate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The acute oral toxicity of sodium bisulfate is low. The acute oral LD₅₀ in male rats was 2,800 mg/kg. It was minimally irritating to the rabbit's skin and mildly irritating to the eyes. An acute inhalation study was available with sodium sulfate. Inhalation toxicity was not observed at 0.01 mg/l (the only dose tested). No dermal toxicity or dermal sanitization studies were available in the database.

Due to the lack of data for sodium bisulfate, both human metabolic processes and toxicity data for sodium sulfate were used for the risk characterization. Both sodium bisulfate and sodium sulfate readily undergo hydrolysis and dissociate to sodium ions and sulfate ions in the body.

Sodium sulfate was administered to male Sprague-Dawley rats at a dietary concentration of 0.84% (approximately 320-400 mg/kg/day) for 27 and 44 weeks. There was no mortality, tumors, body weight change or significant changes in food and/or water consumption. The NOAEL was ~320-400 mg/kg/day. In another study, male Sprague-dawley rats were given in diet 0.0, 0.125, 0.250, 0.5, 1 and 2% sodium sulfate (approximately 0, 125, 250, 500, 1,000 and 2,000 mg/kg/day) for 4 weeks. No changes in food and water consumption, body weight gain, food conversion efficiency, urine production or diarrhea. Blood hemoglobin, white blood count, serum alkaline phosphatase, inorganic phosphate and gross organ pathology were also unaffected. The NOAEL was 2,000 mg/kg/day (highest dose tested). A LOAEL was not observed in this study.

Sodium sulfate showed no mutagenic effect in the Ames test using various strains of *S. typhimurium* (TA1535, TA1537, TA100, TA98) both with and without S9 activation.

No carcinogenicity studies were available in the database. The National Toxicology Program (NTP), International Agency for Research on Cancer (IARC), and Occupational Safety &

Health Administration (OSHA) have not listed sodium bisulfate as a carcinogen. A DEREK analysis was performed on sodium bisulfate and no structural alerts were detected. EPA concluded that sodium bisulfate is unlikely to pose a carcinogenic risk to humans based on lack of mutagenicity concerns for sodium sulfate, lack of any structural alerts for carcinogenicity, lack of any systemic toxicity at doses up to 2,800 mg/kg/day, and its metabolism to form a sulfate which is natural constituent present in the body.

Sodium sulfate was included in a test of a method for rapid assessment of teratogenicity. Pregnant ICR/SIM mice were given a saturated aqueous solution of sodium sulfate orally by gavage to deliver a dose of 2,800 mg/kg/ day on days 8-12 of gestation. No maternal deaths occurred and the average maternal weight gain during the treatment period was not significantly different from that of water-treated controls. Twenty-four litters were delivered alive, and none were resorbed. The mean numbers of neonates delivered alive and dead in each litter and the survival of neonates on day 3 were not statistically significantly different from those of controls. Only body weight on day 1 was statistically significantly greater than that of controls. The maternal and developmental NOAEL = 2,800 mg/kg bw, the only dose tested.

No immunotoxicity, neurotoxicity or reproductive toxicity studies were available in the database.

Sodium bisulfate mammalian metabolism is essentially that of the sodium cation and sulfate anion. As previously noted, when sodium bisulfate is added to food products containing water or after ingestion of sodium bisulfate it ionizes to sodium ions, hydrogen ions and sulfate ions. Following ingestion, sulfate anions are predominantly not absorbed from the gastrointestinal tract and are excreted unchanged in urine. However, the sulfate anion is a

normal constituent in the body, predominantly resulting from the body's metabolism of sulfur-containing food sources such as foods containing the essential amino acids cysteine and methionine. Sulfate anions are vital components in a number of human biosynthetic pathways such as cartilage production and the formation of pancreatic digestive enzymes. Additionally, the sulfate anion is also an important conjugate in the Phase II conjugation/ elimination of oxidized (OH) aromatic ring metabolites and for hydroxyl steroid hormones, such as estrogen, where it acts as a transport agent to target organ tissue receptors.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

There was no hazard identified in repeat dose developmental studies at the limit dose of 2,800 mg/kg/day of sodium sulfate to either parental animals or their offspring. No effects were seen in two subchronic oral toxicity up to approximately 2,000 mg/kg/day of sodium sulfate. Based on the metabolism of sodium bisulfate to sulfate and sodium ions, both of which are essential components in the human metabolic processes, there is a lack of toxicological concern. Thus, due to its low potential hazard and lack of hazard endpoint, the Agency has determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sodium bisulfate, EPA considered exposure under the proposed exemption from the requirement of a tolerance (40 CFR 180.940(a)) such as food in contact with sanitized counters in public eating places, utensils, dairy processing equipment and food processing equipment as well as other uses which may result in dietary exposure.

However, because no hazard was identified for the acute and chronic dietary assessment (food and drinking water), or for the short-, intermediate-, and long-term residential assessments, no quantitative aggregate exposure assessments were performed.

2. *Dietary exposure from drinking water.* Residues of sodium bisulfate from uses in food contact sanitizing solutions, utensil, dairy processing equipment and food processing equipment may enter drinking water. However, because no hazard was identified for the acute and chronic dietary assessment, or for the short-, intermediate-, and long-term residential assessments as listed in this unit, no quantitative aggregate exposure assessments were performed.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Residential (dermal and inhalation) exposure from food contact surface sanitizing solutions for public eating places, dairy-processing equipment, food-processing equipment and utensils are possible. Since an endpoint for risk assessment was not identified, a quantitative residential exposure assessment for sodium bisulfate was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found sodium bisulfate to share a common mechanism of toxicity with any other substances, and sodium bisulfate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sodium bisulfate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

The toxicity database for sodium bisulfate is adequate for assessment of risks to infants and children and the potential exposure is adequately characterized given the low toxicity of the chemical and formation of sulfate ion. No hazard was identified and there is no residual

uncertainty regarding prenatal and/or postnatal toxicity. No acute or subchronic neurotoxicity studies are available, but there were no clinical signs of neurotoxicity or any systemic toxicity observed in the available database at doses up to 2,800 mg/kg/day. No developmental, reproductive, or teratogenic effects were seen in the available studies at doses up to and including 2,800 mg/kg/day.

Based on this information, there is no concern at this time for increased sensitivity to infants and children to sodium bisulfate when used as an inert ingredient in pesticide formulations for food contact surface sanitizing applications and a safety factor analysis has not been used to assess risk. For the same reason, EPA has determined that an additional safety factor is not needed to protect the safety of infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on sodium bisulfate, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to sodium bisulfate under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180. 940(a) for residues of sodium bisulfate when used as an inert ingredient in pesticide formulations applied to food contact surface sanitizing solutions for public eating places, dairy processing equipment, food processing equipment and utensils at no more than 2,000 ppm in formulation, is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of sodium bisulfate in or on any food commodities. EPA is establishing a limitation on the amount of sodium bisulfate that may be used in pesticide formulations. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution that contains greater than 2,000 ppm of sodium bisulfate in the pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for sodium bisulfate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for sodium bisulfate (CAS Reg. No. 7681-38-1) when used as an inert ingredient in antimicrobial pesticide formulations applied to food contact surface sanitizing solutions for public eating places, dairy processing equipment, food processing equipment and utensils at no more than 2,000 ppm in formulation.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 2, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.940, in the table in paragraph (a), alphabetically add the following inert ingredient to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
*	* *	* *
Sodium bisulfate	7681-38-1	When ready for use, the end-use concentration is not to exceed 2,000 ppm
*	* *	* *